JUN 2 0 2000

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

K001733

Summary of Safety and Effectiveness

- **Submitted By:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, Indiana 46581-0708
  219-267-6131

- **Contact Person:**

  Fred McClure
  Regulatory Affairs Associate
  Telephone: 219-372-4294
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- **Date:**

  May 30, 2000

- **Trade Name:**

  Zimmer Poly Plug™ Intramedullary System and Allen Medullary Plugs

- **Common Name:**

  Cement Obturator

- **Classification Name:**

  Surgical Mesh

- **Predicate Devices:**

  - Fuson Bone Plug, Radiopaque (Zimmer, Inc.), K800142
  - ZCH Alpha Hip Prosthesis w/PMMA Precoat (Zimmer, Inc), K950312
  - ORTHOSORB Absorbable Cement Restrictor (Johnson &Johnson), K932595

Summary Of Safety And Effectiveness
(Continued)

- **Device Description**

Intramedullary bone plugs are made from polyethylene. They are inserted into the intramedullary canal prior to the introduction of bone cement and insertion of the appropriate prosthesis. The plugs are used to prevent the flow of cement distal to the prosthesis, introduce greater cement penetration into cancellous bone interstices, and facilitate subsequent removal of cement if this becomes necessary.

The *Zimmer Poly Plug* is molded from high-density polyethylene (HDPE) with 10 percent barium sulfate to provide radiopacity. The edges of the *Zimmer Poly Plug* are threaded to help wedge the plug in the canal during insertion. Notches on the proximal surface contract as the plug is inserted and expand after the inserter instrument is removed to provide a friction fit in the medullary canal. The *Zimmer Poly Plug* is available in seven different sizes.

The Allen Medullary Plugs will have the option of being molded from HDPE with 10 percent barium sulfate for radiopacity or machined from UHMWPE. The Allen Medullary Plug has a double flanged geometry. The proximal flange provides a proximal barrier, while the more flexible distal flange forms a secondary seal to prevent cement leakage. The Allen Medullary Plug is also available in seven different sizes.

Sizes and Configurations

See engineering drawings and component listing in Exhibit A.

Drawings

Engineering drawings of intramedullary cement plugs can be found in Exhibit A.

- **Intended Use**

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control and restrict the flow of cement.

The use of a cement plug is essential for the introduction of low viscosity cement into the intramedullary canal by means of a cement applicator.

Implanting the orthopedic component into the closed space aids in pressurization and induces cement penetration into cancellous bone interstices which helps to optimize the cement/bone interface while minimizing voids. Using the intramedullary cement plug also prevents cement flow into the distal part of the

medullary canal and facilitates subsequent removal of cement if this becomes necessary.

The larger intramedullary cement plugs are useful in revision surgeries where a wide, smooth intramedullary canal must be plugged.

- **Comparison to Predicate Devices**

  In function and overall design, the intramedullary cement plugs are equivalent to other commercially available intramedullary cement plugs currently on the market. These devices include those cleared in:

  - Fuson Bone Plug, Radiopaque (Zimmer, Inc.), K800142
  - ZCH Alpha Hip Prosthesis w/PMMA Precoat (Zimmer, Inc), K950312
  - ORTHOSORB Absorbable Cement Restrictor (Johnson & Johnson), K932595

  Information on these predicate devices and a table providing comparison is contained in Exhibit D.

RA05001K.510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2000

Mr. Fred McClure
Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K001733
Trade Name: Zimmer PolyPlug Intramedullary System and Allen Medullay Plugs
Regulatory Class: II
Product Code: JDI, LZN
Dated: May 30, 2000
Received: June 7, 2000

Dear Mr. McClure:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit F

510(k) Number (if known K001733

Device Name:

Zimmer Poly Plug™ Intramedullary System and Allen Medullary Plugs

Indications For Use:

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control and restrict the flow of cement.

The use of a cement plug is essential for the introduction of low viscosity cement into the intramedullary canal by means of a cement applicator.

Implanting the orthopedic component into the closed space aids in pressurization and induces cement penetration into cancellous bone interstices which helps to optimize the cement/bone interface while minimizing voids. Using the intramedullary cement plug also prevents cement flow into the distal part of the medullary canal and facilitates subsequent removal of cement if this becomes necessary.

The larger intramedullary cement plugs are useful in revision surgeries where a wide, smooth intramedullary canal must be plugged.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001733